

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p>PLAINTIFFS' OPPOSITION TO THE ROCHE DEFENDANTS' SUPPLEMENTAL MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS</p>

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

INTRODUCTION

Hoffman La Roche, Inc. and Roche Laboratories Inc.'s, ("Roche") individual memorandum (hereinafter "Roche MTD") seeks the dismissal of all of plaintiffs' claims on the grounds that the Consolidated Complaint does not allege any facts that, if proven, would support a cause of action against Roche. Contrary to Defendants' assertion, plaintiffs have made sufficient allegations to sustain its claims against Roche.

Plaintiffs allege fraudulent AWP's for all Roche drugs for which they seek relief and properly use a generally available market price to demonstrate one outrageous Roche spread.¹ Although it applies to only one drug, this spread alone provides the requisite specificity required by Fed. R. Civ. P. 9(b) and this Court's prior rulings in *County of Suffolk v. Abbott Labs., et al.* (Civ. Action No. 1:03-cv-10643)(MDL 1456).²

Roche also argues that all of plaintiffs' claims for physician-administered drugs should be dismissed because these are reimbursed based on actual cost. Roche overstates this point, as detailed in Point C below.

DISCUSSION

A. Plaintiffs' Fraud-Based AWP Claims Are Pled With Sufficient Particularity And Should Be Sustained.

Roche contends that plaintiffs never supported the source of their "market prices" and as such plaintiffs have not adequately pleaded the basis for their spread calculations. Roche MTD at 4.

¹ See Corrected Consolidated Complaint, filed on June 22, 2005 ("Consolidated Complaint" or "CC") at ¶¶527, CC Exh. A; Nassau Second Amended Complaint, filed on January 6, 2006 ("Nassau SAC" or "NSAC") at ¶¶ 443-441, NSAC Exh. B.

² See *In re Pharm. Indus. Average Wholesale Price Litig.*, 339 F.Supp.2d 165, 173 ("Suffolk I"); *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257, 2004 WL 2387125, at *3 (D. Mass. Oct. 26, 2004) ("Suffolk II"); *In re Pharm. Indus. Average Wholesale Price Litig.*, Memorandum and Order at 1-2 (D. Mass. April 8, 2005)("Suffolk III")

Contrary to the defendants' contention, plaintiffs already informed the Court and all defendants, including Roche, that the prices used to calculate spreads were actual market prices offered to Ven-a-Care of the Florida Keys, Inc. ("Ven-a-Care"), a licensed pharmacy, and available on a nationwide basis to similar pharmacies.³ See Plaintiffs' Response to Defendants' Request for Extension of Time and Further Relief in Order to Comply with July 8, 2005 Order (filed October 12, 2005). Furthermore, in *State of California ex rel. Ven-a-Care of the Florida Keys v. Abbott Labs., et al.*, also pending before this Court, plaintiffs there utilized the same prices to calculate the spreads in support of similar claims against various drug manufacturers. The legitimacy and source of the same prices used to calculate spread there, as here, were not questioned by any defendant, including Roche, in recently filed motions to dismiss in that action.

In order to maintain fraud-based AWP Claims, plaintiffs must set forth factual allegations regarding spread, internal documents or government investigations from which an inference of fraud can reasonably be made. See *Suffolk II*, 2004 WL 2387125, at *2; *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 187, 209 (D. Mass. 2004) ("*Pharm. III*"). The Court has also required plaintiffs to allege a spread that does not rely upon averaging. See *Suffolk III* at 2. Plaintiffs (1) provide fraudulent AWP for all Roche products for which plaintiffs paid (See CC ¶¶223-5, 230, 234-8, CC Exh. A & B; NSAC ¶¶443-441, NSAC Exh. B); and (2) detail an exorbitant spread calculated based on actual available market prices; and, (3) properly allege and refer to government investigations concerning Medicaid and pricing practices of Roche Group being conducted by the Senate Finance Committee and the House Committee on Energy and Commerce (See CC ¶¶526-528,

³Roche's ignorance of McKesson/ServAll is insincere. See Roche Memo at p 4. From 1994 to at least 2003, McKesson/ServAll was a joint venture between McKesson, one of the top 3 largest drug wholesalers, and ServAll, one of the largest group purchasing organization representing well over 3000 independent pharmacies. See www.query.nytimes.com/gst/fullpage.html?res=9C04E3D91331F933A25751C0A9679C8B63.

NSAC ¶ 438-439). The foregoing is sufficient to draw a reasonable inference of a company-wide AWP Fraud in compliance with the requirements of Fed. R. Civ. P. 9(b). *See U.S. ex rel Franklin v. Parke Davis*, 147 F.Supp.2d 39, 46 (D.Mass 2001) (Saris, J.) (“[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible.”)

Plaintiffs do not dispute that their allegations against Roche may not be as expansive as against other defendants. That alone, however, does not mean that they are insufficient. Roche does not dispute the accuracy of the spread that plaintiffs have alleged, rather they claim the Kytril spread is an isolated data point. Roche MTD at 4. The fact that the data point is isolated is not an exoneration of Roche. Rather, it is an understandable consequence of plaintiffs’ inability-as yet- to access the same data for Roche that they have obtained for other defendants. Similarly, the fact that NY may only be able to allege damages for Kytril in a more limited fashion (given the PAD reimbursement scheme) does not mean that Roche never marketed the spread on its other drugs. Roche created a spread for Kytril for a reason, and that reason was to move its products.

Because the CC adequately alleges marketing of the spread (*see* CC at ¶525), and has otherwise complied with the particularity requirements as detailed above, plaintiffs’ fraud-based AWP claims should be sustained.

B. Plaintiffs’ Fraud-Based Best Price Claims Are Pled With Sufficient Particularity And Should Be Sustained.

In order to maintain Best Price claims, plaintiffs must “set forth minimal facts with respect to (1) the allegedly fraudulent or false price reported to the state for any specific drug; or (2) any information showing a company-wide scheme to misstate Best Prices.” *Suffolk II*, 2004 WL 2387125, at *3.

Plaintiffs have admittedly only done one of these. First, plaintiffs allege the name of every Roche drug for which they assert Best Price claims. *See* CC ¶¶ 223-245, Exh. A & B; NSAC ¶¶ 443-441, Exh. B. Second, plaintiffs allege 1) a government investigation into Roche's pricing practices and 2) that Roche improperly excluded certain nominally priced transactions from its best price reporting. *See* CC at ¶ 529. Thus, while plaintiffs have not tied their allegations to a particular drug, they have alleged a company-wide scheme to improperly exclude certain nominally priced transactions from their best price calculations.

C. Plaintiffs' Claims For Physician-Administered Drugs Should Be Sustained.

Roche contends that all claims for physician-administered drugs should be dismissed because under New York law they are reimbursed based on the actual cost to the physician, not fraudulent WACs and AWP. *See* Roche MTD at 5. Roche's argument is overly-broad.

Plaintiffs assert their claims against Roche "from 1992 to the present." CC ¶1; NSAC ¶1. New York did not begin reimbursing physician-administered drugs based on actual cost until it amended the reimbursement scheme on June 9, 1994. *See* N.Y. Soc. Serv. L. § 367-a(9)(a) (1994 amendments). Prior to June 9, 1994, New York reimbursed physician-administered drugs based on fraudulent AWP. As such, all fraud-based claims between 1992 and June 9, 1994 must be sustained.

Additionally, irrespective of the amendment, to the extent physician-administered drugs can also be self-administered they are reimbursed based on fraudulent AWP and thus plaintiffs' theory of fraud and injury applies. At this stage of the case, there is no record before the Court on which to determine which of Roche's physician-administered drugs are also self-administered and therefore reimbursed based on fraudulent AWP. Thus, the claims should be sustained until the record is

developed and presented to the trier of fact.

Finally, the December 3, 2001 settlement between the State of New York and TAP regarding the marketing, sale and pricing of Lupron (the “2001 Lupron Settlement”) calls into question whether physicians in New York are, in fact, reimbursed based on “actual cost” or AWP. In the context of the 2001 settlement, the State of New York alleged that Lupron’s reimbursement was based on TAP’s reported AWP (despite the New York State statute mandating that physician administered drugs are reimbursed at a acquisition cost). The State further alleged that TAP falsely advised providers that their actual acquisition costs should not be reported to Medicaid as the basis for reimbursement. Rather, TAP counseled physicians that Lupron’s reimbursement claims should be submitted at the inflated AWP. *See* New York State Settlement Agreement, attached as Exhibit A to TAP’s Individual Motion to Dismiss, at II(A) (iii) at 3. At bare minimum, this too presents a question for the trier of fact, not appropriately resolved at this stage of the case.

CONCLUSION

For the reasons set forth herein, Roche’s motion should be denied. Should the court grant Roche’s motion, plaintiffs expressly request that any dismissal of their claims be without prejudice so the plaintiffs may re-plead when and if (1) the ongoing senate investigation produces relevant evidence of improper use of the nominal pricing exception and/or (2) plaintiffs’ ongoing investigation produces additional evidence of misconduct by Roche.

Dated: April 17, 2006

Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

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